



State of Maine  
Department of Health and Human Services  
11 State House Station  
Augusta, Maine  
04333-0011

Office of Attorney General  
6 State House Station  
Augusta, Maine  
04333-0006

**TO:** Interested Parties

**FROM:** Anthony Marple, Director, Office of MaineCare Services; and  
Linda J. Conti, Assistant Attorney General

**SUBJECT:** **Final Rule:** Department of Health and Human Services, 10-144, Chapter 275-Reporting Requirements for Pharmaceutical Manufacturers and Labelers; Office of the Attorney General, 26-239, Chapter 111, Reporting Requirements for Pharmaceutical Manufacturers and Labelers.

**DATE:** November 2, 2009

This letter gives notice of a final rule: Department of Health and Human Services, 10-144, Chapter 275-Reporting Requirements for Pharmaceutical Manufacturers and labelers; Office of the Attorney General, 26-239, Chapter 111, Reporting Requirements for Pharmaceutical Manufacturers and Labelers. This final rulemaking clarifies Maine requirements for clinical trial registration and results reporting, compatible with current and anticipated Federal reporting requirements and with the capabilities of the publicly funded website, [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). The rule modifies the scope of the trials required to be registered and reported. It includes requirements to report on observational studies and clarifies the requirements of reporting post hoc analysis of trial results. This rulemaking provides contact information and clarifies the application of penalty for violations. This rule change does not require reposting of previously posted trials. Other minor technical, grammatical and structural changes are included within this rulemaking. This rule change is not anticipated to have any adverse impact on small business.

Rules and related rulemaking documents may be reviewed and printed from the Office of MaineCare Services website at [http://www.maine.gov/dhhs/oms/rules/provider\\_rules\\_policies.html](http://www.maine.gov/dhhs/oms/rules/provider_rules_policies.html) or for a fee, interested parties may request a paper copy of rules by calling 207-287-9368. For those who are deaf or hard of hearing and have a TTY machine, the TTY number is 1-800-423-4331.

A concise summary of the proposed rule is provided in the Notice of Agency Rule-making Proposal. This notice also provides information regarding the rule-making process. Please address all comments to the agency contact person identified in the Notice of Agency Rule-making Proposal. Persons with questions regarding the policy should contact Linda J. Conti from the Office of Attorney General at (207) 626-8591

## **Notice of Agency Rule-making Adoption**

**AGENCY:** Department of Health and Human Services, Office of MaineCare Services

**CHAPTER NUMBER AND TITLE:** This letter gives notice of a final rule: Department of Health and Human Services, 10-144, Chapter 275, Reporting Requirements for Pharmaceutical Manufacturers and labelers; Office of the Attorney General, 26-239, Chapter 111, Reporting Requirements for Pharmaceutical Manufacturers and Labelers.

### **ADOPTED RULE NUMBER:**

**CONCISE SUMMARY:** This letter gives notice of a final rule: Department of Health and Human Services, 10-144, Chapter 275-Reporting Requirements for Pharmaceutical Manufacturers and labelers; Office of the Attorney General, 26-239, Chapter 111, Reporting Requirements for Pharmaceutical Manufacturers and Labelers. This final rulemaking clarifies Maine requirements for clinical trial registration and results reporting, compatible with current and anticipated Federal reporting requirements and with the capabilities of the publicly funded website, [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). The rule modifies the scope of the trials required to be registered and reported. It includes requirements to report on observational studies and clarifies the requirements of reporting post hoc analysis of trial results. This rulemaking provides contact information and clarifies the application of penalty for violations. This rule change does not require reposting of previously posted trials. Other minor technical, grammatical and structural changes are included within this rulemaking. This rule change is not anticipated to have any adverse impact on small business.

See [http://www.maine.gov/bms/rules/provider\\_rules\\_policies.htm](http://www.maine.gov/bms/rules/provider_rules_policies.htm) for rules and related rulemaking documents.

**EFFECTIVE DATE:** November 2, 2009

**AGENCY CONTACT PERSON:** Nicole Rooney, Health Planner  
**AGENCY NAME:** Division of Policy and Performance  
**ADDRESS:** 442 Civic Center Drive  
11 State House Station  
Augusta, Maine 04333-0011  
**TELEPHONE:** (207)-287-4460 FAX: (207) 287-9369  
TTY: 1-800-423-4331 or 207-287-1828 (Deaf/Hard of Hearing)

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**10-144, Chapter 275: DEPARTMENT OF HEALTH AND HUMAN SERVICES  
(a joint rule with)  
26-239, Chapter 111: OFFICE OF ATTORNEY GENERAL  
REPORTING AND FEE REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURERS  
AND LABELERS**

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<b>SECTION 1</b>	<b>PRESCRIPTION DRUG CLINICAL TRIAL REPORTING</b>	<b>ESTABLISHED 3/1/07 UPDATED 11/02/09</b>
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**SECTION 1                      PRESCRIPTION DRUG CLINICAL TRIAL REPORTING      ESTABLISHED 3/1/07  
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**SECTION 1      PRESCRIPTION DRUG CLINICAL TRIAL REPORTING**

**1.01      STATUTORY AUTHORITY AND PURPOSE**

These regulations were originally adopted March 1, 2007, pursuant to 22 M.R.S.A. §2700-A (7) and 5 M.R.S.A. §207(2) to define the obligations of manufacturers and labelers of prescription drugs and biological products to publicly disclose on Internet websites information about clinical trials of drugs or biological products that are or have been FDA-approved for marketing and are or have been dispensed, administered, delivered or promoted in Maine, thereby protecting consumers and informing prescribers and enhancing the role of this State as guardian of the public interest. Medical devices are excluded from the scope of these regulations unless they are a combination of device and drug whose primary mode of action renders them subject to FDA-regulation as a drug.

**1.02      DEFINITIONS**

1.02-1 Affiliate means a business entity that has a relationship with a second business entity if, directly or indirectly, one business entity controls or has the power to control the other business entity, or a third party controls or has the power to control both of the business entities. A business entity controls another if it owns more than fifty percent (50%) of the equity interest or exercises a controlling influence over the management and policies of the other.

1.02-2 Clinical trial means (a) an hypothesis-testing “clinical investigation,” as defined by the federal Food and Drug Administration (“FDA”) in section 312.3(b) of Title 21 of the Code of Federal Regulations (CFR), that is intended to test the safety or effectiveness of a therapeutic drug or biological product with one (1) or more human subjects; and the results of which either have been or are intended to be submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit, but excluding Phase I trials; and (b) any post-marketing, non-Phase I clinical study or investigation by the manufacturer or labeler on the safety or efficacy of an FDA-approved prescription drug or biological product, including investigations of off-label uses and observational (non-interventional) studies; and (c) any study testing the bioequivalency of a drug against the innovator drug or biological product, or against another drug or biological product.

1.02-3 Clinical trial conducted or sponsored means a clinical trial which a manufacturer or labeler is sponsoring or has sponsored, irrespective of whether the trial is or was continued to completion.

1.02-4 Clinical trial initiation date means the date that patient enrollment begins.

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1.02    DEFINITIONS (Cont.)

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|-----------------|--|
| Eff.<br>11/2/09 | 1.02-5    Completion date or completed means the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated. If there is more than one primary outcome measure, the completion date is the date of the final collection of data for the last primary outcome measure.  |
| Eff.<br>11/2/09 | 1.02-6    Covered clinical trial means a clinical trial initiated on or after October 15, 2002, and conducted or sponsored by the manufacturer or labeler of any drug or biological product, or medical device delivering a drug or biological product, which trial is or has been FDA-approved for marketing for any use and dispensed, administered, delivered or promoted in Maine. A clinical trial conducted outside the United States is not a covered clinical trial unless (a) one or more trial sites are within the United States or its territories, or (b) the results of which either have been or are intended to be submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit; or (c) the results of the trial are relied upon by a manufacturer or labeler for claims made in marketing, promotional or educational efforts or materials to prescribers or consumers in Maine. |
| Eff.<br>11/2/09 | 1.02-7    Department means the State of Maine Department of Health and Human Services.   |
|                 | 1.02-8    Hypothesis-Testing clinical investigation means a clinical trial that tests a specific clinical hypothesis. Hypothesis-testing clinical investigations are the same as “clinically directive trials” or “confirmatory trials,” are intended to examine pre-stated questions (i.e., to test hypotheses) using pre-determined, statistically valid plans for data analysis and are intended to provide firm evidence of safety and/or effectiveness.   |
|                 | 1.02-10    Labeler means a person or entity that (a) receives prescription drugs or biological products from a manufacturer or wholesaler; (b) repackages the drugs or biological products for later resale; and (c) has a labeler code from the federal Food and Drug Administration under section 207.20 of Title 21 of the Code of Federal Regulations.   |
|                 | 1.02-11    Manufacturer means (a) a manufacturer of prescription drugs or biological products, and (b) affiliates of the manufacturer.   |
|                 | 1.02-12    Publicly accessible Internet website means any publicly accessible Internet website, or any publicly accessible portion of an Internet website, that can be searched electronically at no cost to the searcher and without requiring registration or provision of personal information by the searcher as a condition for access and that prominently identifies the sponsor of the website.  |

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1.02    DEFINITIONS (Cont.)

1.02-13    Publicly funded Internet website means the Internet website of the National Institutes of Health, [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), or its successor.

1.02-14    Sponsor means a person who takes responsibility for and initiates a clinical investigation. A person other than an individual, such as a corporation or an agency, which uses one (1) or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor; its employees in this instance are investigators. A person who does not initiate a clinical investigation but who actually conducts the investigation is not a sponsor but is an investigator.

1.03    DISCLOSURE OF TRIALS OF DRUGS AND BIOLOGICAL PRODUCTS

1.03-1    Trial Registry Data. A manufacturer or labeler shall register each covered clinical trial by posting on a publicly funded Internet website the following information with respect to that trial:

- A.      Trial identifying information consisting of a unique trial number and any externally used secondary IDs,
- B.      The protocol title intended for the lay public, and any acronym or initials used to identify the study;
- C.      The official scientific title of the study and (or including) the name of the intervention, the condition being studied and the intended outcome;
- D.      The nature of the investigation, i.e., whether interventional, observational or an expanded access, as those or other terms are used in the context of the publicly funded website, and whether the investigation includes an FDA-regulated intervention;
- E.      The name of the organizations (up to 10) providing funding;
- F.      The name of all sponsors, or in the alternative the principal investigator if designated by the sponsor, grantee, contractor or awardee (so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial and has the ability to meet all of the requirements for the

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1.03	DISCLOSURE OF TRIALS OF DRUGS AND BIOLOGICAL PRODUCTS (Cont)
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submission of clinical trial information) including the official title, and the relevant organizational affiliation;

G.     A short description of the protocol, including a brief statement of the study hypothesis;

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H.     The date the protocol information was last verified;

I.     The overall recruitment status, and if the investigation was suspended, terminated or withdrawn, a brief explanation of the reason(s);

J.     The date of the start of enrollment to the protocol; the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome; and the final date on which data was collected, or expected to be collected;

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K.     The availability and status of the drug or biological product outside any clinical trial protocol;

L.     For interventional investigations, the primary investigative techniques used in the protocol, including:

1.    The phase of the investigation, as the phase is defined by the United States Food and Drug Administration;
2.    The intervention model of the investigation;
3.    The number of intervention groups;
4.    The masking used;
5.    The method of allocation of participants;
6.    The primary purpose of the investigation;
7.    The targeted or actual enrollment;

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M.     For observational studies, the primary strategy for participant identification and follow-up, including:

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**1.03                      DISCLOSURE OF TRIALS OF DRUGS AND BIOLOGICAL PRODUCTS (Cont.)**

1. The time perspective used in the investigation (observation period relative to participant enrollment);
2. The biospecimen retention policy, including information on all types of biospecimens retained;
3. The targeted or actual enrollment;
4. The number of study or participant groups;

N. The primary outcome measure, including the specific measure used to determine effect, the time frame by which the measure is assessed, and whether the measure is a safety issue;

O. All secondary outcome measures, including the specific measure used to determine effect, the time frame by which the measure is assessed, and whether the measure is a safety issue;

P. Arms, groups and interventions, including:

1. For interventional studies, for each arm:
  - a. The short name used to identify the arm;
  - b. The arm type;
  - c. A brief description of the arm;
2. For observational studies:
  - a. The short name to identify each participant group;
  - b. An explanation of the nature of the study or participant group;

Q. The type of intervention, a brief descriptive name of the type of intervention, a description giving key details of the intervention, identification of which arms or groups designated for the intervention, and any other names used to identify the intervention;

R. The primary disease or condition being studied, or the focus of the investigation, and key words or phrases that best describe the protocol;

S. For observational studies, a description of the population from which the groups are selected, and a description of the probability or non-probability sample;

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1.03                      DISCLOSURE OF TRIALS OF DRUGS AND BIOLOGICAL PRODUCTS (Cont.)

- T.      A description of summary criteria, i.e., key characteristics for determining eligibility to participate for selection of participants, including gender and, age limits and acceptance of healthy volunteers;
- U.      Name and location where the protocol is conducted;
- V.      Contact information for the facility, by either phone or email, or for a central contact person and second contact person X. The names, degrees, roles and affiliations of the principal investigator and other persons responsible for overall scientific leadership of the protocol;
- W.      Once available, links or citations to all articles by any of the clinical trial investigators published in a peer-reviewed medical journal summarizing the safety or efficacy results of the clinical trial; and
- X.      The following links:
  - 1.      If applicable, a link to the publicly accessible Internet website to which the manufacturer or labeler retains a posting of clinical drug trials on the investigated drug in compliance with the Maine rule; and
  - 2.      Once available, a link or links to a publicly accessible website containing FDA-approved labeling information regarding the reporting manufacturer's or labeler's drug, and information of a Class 1 or Class II recall, of a market alert by the FDA; and
  - 3.      Once available, a link or links to any applicable medical product safety alert by the FDA regarding the reporting manufacturer's or labeler's drug.

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- 1.03-2 Trial Results Data. A manufacturer or labeler shall post on a publicly funded Internet website information concerning the results of each completed or discontinued covered clinical trial. The manufacturer or labeler shall complete all of the following reporting categories: Results Point of Contact, Certain Agreements, Participant Flow, Baseline Characteristics, Outcome Measures, and Adverse Events. All mandatory data elements and all other relevant ("optional") data elements must be completed (provided the data are available for the optional data element). For purposes of completing the Adverse Events reporting module, if no threshold is specifically required on the publicly funded website for the reporting of "other" adverse events, a threshold of five (5) percent is required. The requirement to post results should be construed in light of the purpose that the information be valid, internally consistent, logical and meaningful, and producing tables that are

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clear and precise, so that the full range of readers reasonably can be expected to understand the information.

The manufacturer or labeler also shall submit for posting any post hoc analysis of clinical trial data by or on behalf of the manufacturer or labeler that represents a deviation or correction from previously reported results of an interventional study on the safety or efficacy of the drug, if the deviation or correction will be objectively significant to a prudent prescriber of the drug.

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1.03-3 Identification Information. In the case of any drug or biological product for which a covered clinical trial has been registered in accordance with §1.03-1, the manufacturer or labeler shall submit, and maintain and promptly update, the following information for the drug or biological product to a publicly funded Internet website:

- A.        The generic name of the drug or biological product;
- B.        The FDA New Drug Application (NDA) number, if available, of the drug or biological product;
- C.        All known current and former names/aliases used externally for the drug or product (serial numbers, code names, chemical descriptions, brand names, etc.) including identifications in any marketing materials; and
- D.        The unique identifiers used in all postings of trial information and trial results of the drug or biological product, and all trials used in the NDA along with any other trials and results which are required to be posted under this rule, and identification by the clinicaltrials.gov registry number if available.

1.03-4 Reliability. The manufacturer or labeler is responsible for the posting of information in accordance with sections 1.03-1, 1.03-2 and 1.03-3 that is reliable, accurate and true. The manufacturer or labeler is responsible for maintaining the reliability, accuracy and truthfulness of a posting.

1.03-5 Posting Date. In the case of posting to the publicly funded Internet website of the National Institutes of Health or its successor agencies, information shall be deemed to be posted on the date that information submitted by the manufacturer or labeler is received by the agency or its agent responsible for administering the website.

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If the registration or results information has not appeared on such publicly funded website within ninety (90) days after submission to the agency, the manufacturer or labeler shall make written notification within the next thirty (30) days to the Department unless the information appears on the publicly funded website in the interim. This notice shall provide any information known to the manufacturer or labeler with respect to the specific date by which the information will appear, the

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reasons for the delay and the actions previously taken and to be taken in the future by the manufacturer or labeler to ensure posting on such publicly funded website. A manufacturer or labeler in compliance with this paragraph is exempted from the applicable time requirement insofar as it demonstrates that the cause of the delay is and remains solely the agency's or its website.

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1.03-6 Exemptions from revisions. Investigations or studies registered prior to January 1, 2010, are exempt from newly imposed revisions within section 1.03-1 of this rule. Results of investigations or studies submitted for posting prior to January 1, 2010, are exempt from newly imposed revisions within section 1.03-2, except that the requirement to report post hoc analysis applies if the analysis was completed after January 1, 2010, regardless of the date of the previously reported results. Any posting requirement preceding the adoption of revisions of this rule does not qualify as a newly imposed requirement. Observational (non-interventional) investigations or studies completed prior to January 1, 2010, are exempt from any newly created application of this rule.

1.04                      SUBMISSION SCHEDULE

1.04-1                  Clinical Trial Registries

- A.                      Completed or discontinued covered clinical trials. In the case of any completed or discontinued covered clinical trial, the manufacturer or labeler shall post the information described in section 1.03-1 by the latest of the applicable dates below:
- (1)                    the first date the drug or biological product is either dispensed, administered, delivered or promoted in this State for any indication; or
- (2)                    twenty-one (21) days after patient enrollment has begun.
- B.                      The manufacturer or labeler shall have 120 days after the adoption of revisions to these rules to post the information described in section 1.03-1 on trials not previously required to be reported by these rules.

1.04-2                  Clinical Trial Results Databases.

- A.                      In the case of any completed or discontinued covered clinical trial, the manufacturer or labeler shall post the information described in section 1.03-2 in accordance with the following schedule:
- (1)                    one (1) year (plus provided extensions) after the date on which the trial was completed; or

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104. SUBMISSION SCHEDULE (cont)

- (2) the first date the drug or biological product is either dispensed, administered, delivered or promoted in this State, if later than paragraph (1) above.

- B. Information regarding trials discontinued for reasons of safety. In the case of any covered clinical trial discontinued for reasons of safety as determined either by the sponsor of the trial or by the data safety and monitoring board, the manufacturer or labeler shall post information describing the reasons for terminating the trial, especially noting any discernable threat (not previously disclosed on the label) to patient health from existing use by the public of a drug or biological product, within thirty (30) days of the cessation of the clinical trial.

The manufacturer or labeler shall post the information otherwise described in section 1.03-2 within one (1) year after the date on which the trial ceased, or , within 120 days after the adoptions of revisions to these rules, whichever is later. The deadlines for discontinued trials are not subject to extensions.

- C. Extensions. A manufacturer or labeler may delay the posting of information through an extension, as follows:
  - 1. An extension of time granted for good cause by the National Institutes for Health for posting of information described in section 1.03-2 shall be recognized by the Department and permitted under this rule, or
  - 2. In the case of a covered clinical trial (other than a discontinued trial) in which the compilation and analysis of the data are not sufficiently complete to post the information described in section 1.03-2 within one (1) year after the date on which the trial was completed, a manufacturer or labeler may delay the posting of such information twice by up to six (6) months (per delay) provided that the manufacturer or labeler timely submits for posting in substitution of such information a statement that the posting is delayed, an explanation of the circumstances that justify the delay, and the anticipated date that the information will be posted. Including compilation or analysis extensions provided by this paragraph, the time permitted for posting information described in section 1.03-2 may not exceed twenty-four (24) months in total.
- D. Post hoc analysis. The manufacturer or labeler has a continuing duty to post information from a post hoc analysis meeting the criteria of Section 1.03 above. Submissions of post hoc analysis shall include the identification of the dates of any changes from previously posted information.

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1.04                      SUBMISSION SCHEDULE (cont)

1.04-3      Identification Information

Identification in trials. In the case of any completed or discontinued covered clinical trial, the manufacturer or labeler shall post the information described in section 1.03-3 by the latest of the applicable dates below:

- (1)      the first date the drug or biological product is either dispensed, administered, delivered or promoted in this State;
- (2)      twenty-one (21) days after patient enrollment has begun;
- (3)      the date on which the trial is registered with the publicly funded website.

1.04-4      Trials of generics. In the case of any covered clinical trial for bioequivalency, the subject generic shall be treated under the submission schedule set forth in §§1.04-1, 1.04-2 and 1.04-3 as an entirely new drug insofar as the timing of posting of information. For example, even if the name-brand drug was being dispensed in this State, a trial for bioequivalency of the generic alternative would not be required by these rules to be registered under Paragraph (1) of §1.04-1 until the generic drug is either dispensed, administered, delivered or promoted in this State.

1.05      LINKING BY DEPARTMENT WEBSITE

1.05-1      Maintaining links. The Department may maintain a publicly-accessible website containing a link to a publicly-funded Internet website on which covered clinical trials are registered and links to other publicly funded or publicly-accessible Internet websites on which covered clinical trial results are posted. The Department website may be [http://www.maine.gov/dhhs/boh/clinical\\_trials.htm](http://www.maine.gov/dhhs/boh/clinical_trials.htm) or another designated website. The Department retains the discretion as to the links it will list.

1.05-2      Reporting links. In regard to result, covered clinical trials not reported on a publicly-funded Internet website but reported on a publicly-accessible Internet website under former rules, a manufacturer or labeler shall inform the Department in writing of the publicly-accessible Internet website upon which its clinical trial results data are posted so that the Department may create linkages to such websites. The manufacturer or labeler also shall inform the Department in writing if it discontinues use of any website previously linked.

1.05-3      Department contact. Communications with the department are properly directed to: OMS Pharmacy Unit, Clinical Trials Reporting, Maine Department of Health and Human Services, 442 Civic center Drive, 11 State House Station, Augusta, Maine 04333.

**10-144, Chapter 275: DEPARTMENT OF HEALTH AND HUMAN SERVICES  
(a joint rule with)  
26-239, Chapter 111: OFFICE OF ATTORNEY GENERAL  
REPORTING AND FEE REQUIREMENTS FOR PHARMACEUTICAL MANUFACTURERS AND  
LABELERS**

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**SECTION 1                      PRESCRIPTION DRUG CLINICAL TRIAL REPORTING      ESTABLISHED 3/1/07  
LAST UPDATED: 11/02/09**

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1.06      PENALTIES

Each day on which a manufacturer or labeler is in violation of 22 M.R.S.A. §2700-A or these rules with respect to a clinical trial constitutes a separate violation punishable under the Maine Unfair Trade Practices Act, 5 M.R.S.A. §205-A *et seq.*